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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Dosuk D. Lee et al.	Confirmation No.:	2121
Serial No.:	09/284,297	Art Unit:	1615
Date Filed:	July 5, 2000	Examiner:	Neil S. Levy
Customer No.:	21559		
Title:	METHOD OF PREPARING A POORLY CRYSTALLINE CALCIUM PHOSPHATE AND METHODS OF ITS USE		

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APPELLANTS' BRIEF ON APPEAL

In support of Appellants' Notice of Appeal that was filed by Appellants on February 23, 2006, and received by the U.S. Patent and Trademark Office on February 27, 2006, in the above-captioned application, Appellants submit this Brief on Appeal.

This Brief on Appeal complies with the requirements of 37 C.F.R. § 41.37 and addresses the issues raised in the Notification of Non-Compliant Appeal Brief dated December 7, 2006, and the Notification of Non-Compliant Appeal Brief dated April 19, 2007. The fee required by § 41.20 (b)(2) for this Brief on Appeal was paid on September 26, 2006. Appended hereto are a Claims Appendix, Related Proceedings Appendix, and an Evidence Appendix.

TABLE OF CONTENTS

Real Party in Interest

The real party in interest is Etex Corporation, the sole assignee of the above-captioned application.

Related Appeals and Interferences

A related application, U.S. Serial No. 10/222,670, is currently on appeal. A decision in Applicants' favor was recently entered by the Board of Appeals in connection with another related application, U.S. Serial No. 09/569,081. There are currently no pending interferences related to this case.

Status of Claims

Claims 1-39, 41, 44-102, 104-110, and 144 are canceled.

Claims 136, 137, 147, and 149 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent format.

Claims 40, 42, 43, 103, 111-135, 138-143, 145, 146, 148, and 150-153 are currently pending, stand rejected in a final Office action mailed August 23, 2005, and are under appeal.

Status of Amendments

No amendments to the claims have been filed subsequent to the final rejection.

Appellants submit herewith a copy of the Terminal Disclaimer, filed on September 26, 2006, which disclaims the patent term that of the present application extends beyond the expiration date of U.S. Patent 6,953,594, and request its entry in the accompanying Amendment. As entry of this Terminal Disclaimer removes the double patenting rejection of claims 43, 127, 128, 133, and 135 over claims 1 and 3 of the '594 patent (previously claims 18 and 21 of U.S.

Serial No. 09/993,739) from this appeal, Appellants respectfully submit that its entry is appropriate. *See* U.S. DEPARTMENT OF COMMERCE, PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 1207 (8th Ed. 2001) (hereinafter "MPEP").

Summary of Claimed Subject Matter

Five independent claims are pending; independent claims 40 and 138 are directed to methods of preparing a bioceramic composition, independent claims 42 and 43 are directed to bioceramic compositions, and independent claim 103 is directed to a method of treating a bone defect.

Independent claim 40 and its dependent claims are directed to a method of preparing a bioceramic composition by dry mixing powders of a calcium phosphate and a promoter, pressing the dry powders to form a compressed object of a predetermined shape, and hydrating the compressed object to form a reaction product that includes poorly crystalline apatitic (PCA) calcium phosphate. The invention of claims 40, 111-124, and 149-150 is described in the specification on page 11, line 28, through page 12, line 2; page 16, line 24, through page 17, line 7; page 18, lines 19-24; page 20, line 23, though page 21, line 3; page 21, lines 16-21; page 44, line 30, through page 45, line 6; page 51, lines 12-23; pages 61-64; and pages 88-92; and in claims 40, and 111-124, as originally filed.

Independent claim 138 is directed to a method of preparing a bioceramic implant composition by mixing powders of a calcium phosphate and a promoter in a hydrating medium to form a paste, introducing the paste into a mold that approximates a desired implant shape, and allowing the paste to harden. Claim 138 recites that the promoter can be selected from calcium metaphosphate, dicalcium phosphate dihydrate, heptacalcium decaphosphate, calcium pyrophosphate dihydrate, poorly crystalline apatitic (PCA) calcium phosphate, calcium

pyrophosphate, monetite, octacalcium phosphate, CaO, calcium acetate, H_3PO_4, and amorphous calcium phosphate. The invention of claims 138-143, and 145-148 is described in the specification on page 11, line 28, through page 12, line 2; page 16, line 24, through page 17, line 7; page 18, lines 19-24; page 20, line 23, though page 21, line 3; page 21, lines 16-21; page 44, line 30, through page 45, line 6; and page 51, lines 12-23; and in claims 138-148 as originally filed.

Independent claim 42 is directed to a composite material that includes a strongly resorbable, PCA calcium phosphate having a calcium to phosphate ratio (Ca/P) of less than 1.5 (page 12, lines 17-19), which is in contact with a biocompatible supplemental material (page 35, lines 13-16; and page 38, lines 6-7); the biocompatible supplemental material is present in an amount effective to impart a characteristic to the composite material selected from strength, resorption time, adherence, frictional characteristics, release kinetics, tensile strength, hardness, fracture toughness, elasticity, and imaging capability (page 35, lines 19-26; page 37, lines 15-22; page 38, lines 1-4; page 43, lines 2-7; page 44, lines 10-13; page 45, line 31, through page 46, line 2; and page 95, lines 19-22). Claim 42 further requires that the biocompatible supplemental material is a bioresorable material selected from the group consisting of silk, demineralized bone matrix, hyaluronic acid and derivatives thereof, polyorthoesters, polyglycolic acid, polylactic acid, and copolymers thereof, polyesters of α-hydroxycarboxylic acids, poly(L-lactide) (PLLA), poly(D,L-lactide) (PDLLA), polyglycolide (PGA), poly(lactide-co-glycolide (PLGA), poly(D,L-lactide-co-trimethylene carbonate), and polyhydroxybutyrate (PHB), polyanhydrides, poly(anhydride-co-imide), and co-polymers thereof, and bioactive glass compositions; a non-bioresorbable material selected from the group consisting of dextrans, polyethylene, polymethylmethacrylate (PMMA), carbon fibers, polyvinyl alcohol (PVA), poly(ethylene

terephthalate)polyamide, bioglasses, and calcium phosphates; a lubricant selected from the group consisting of silicone oil, polymer waxes, lipids, and fatty acids; or a radiographic material (page 38, lines 13-22; page 43, lines 17-21; page 44, lines 2-5; and page 44, lines 10-25). The invention of dependent claims 152 and 153 is described in the specification on pages 37, lines 25-27, and pages 38, lines 13-17, and in claims 42 and 50-55 as originally filed.

Independent claim 43 is directed to a bioceramic composition, which is a compressed powder object of predetermined shape that includes dry powders of a calcium phosphate and a promoter, which is selected to promote conversion of the calcium phosphate into a strongly resorbable, PCA calcium phosphate (page 44, lines 2-9; page 61, lines 4-8; page 61, line 18, through page 1; and page 63, lines 8-12). The invention of dependent claims 125-137, and 151 is described in the specification on pages 16-22; pages 37-46; pages 61-64; and pages 88-92; and in claims 43, and 125-137, as originally filed.

Independent claim 103 is directed to a method for treating a bone defect by identifying a site for receiving an implant and introducing a compressed powder object at the bone site. The compressed powder object includes dry powders of a calcium phosphate and a promoter and has approximately the shape required for repair of the bone defect. Upon hydration of the compressed powder object at the implantation site, the compressed powder object converts into a strongly bioresorbable PCA calcium phosphate. The invention of claim 103 is described in the specification on pages 16-22; pages 35-37; pages 46-64; and pages 88-92; and in claim 103 as originally filed.

Grounds of Rejection to be Reviewed on Appeal

This appeal presents three issues:

1. Whether the Examiner erred in rejecting claims 40, 42, 43, 111-118, 120, 127-131, 133, and 134 under 35 U.S.C. § 102(e) for anticipation by the '028 patent.

2. Whether the Examiner erred in rejecting claims 40, 42, 43, 111-114, 116-121, 124, 126-135, 138-140, 142, 143, 145, 146, 148, and 150-153 under 35 U.S.C. § 102(e) for anticipation by the '971 patent.

3. Whether the Examiner erred in rejecting claims 40, 43, 103, 111-121, 123-135, 138-143, 145, 146, 148, and 150-153 under 35 U.S.C. § 103(a) for obviousness over the '971 patent in combination with the '162 patent.

Argument

1. The Novelty Rejection

The Legal Standard For Anticipation Under 35 U.S.C. § 102(b)

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). *See also EMI Group North America, Inc. v. Cypress Semiconductor Corp.*, 268 F.3d 1342, 1350 (Fed. Cir. 2001) ("A prior art reference anticipates a patent claim if the reference discloses, either expressly or inherently, all of the limitations of the claim."); MPEP § 2131. *Cf. Schering Corp. v. Geneva Pharm., Inc.*, No. 02-1540, 2003 WL 21767852, at *2 (Fed. Cir. Aug. 1, 2003) ("A patent is invalid for anticipation if a single prior art reference discloses each and every limitation of the claimed invention."); *Crown Operations Int'l, Ltd. v. Solutia Inc.*, 289 F.3d 1367, 1375 (Fed. Cir. 2002) ("A patent is invalid for anticipation when the same device or method, having all of the elements contained in the claim limitations, is described in a single prior art reference.").

"A single reference must describe the claimed invention with *sufficient precision and detail* to establish that the subject matter existed in the prior art." *Verve, LLV v. Crane Cams, Inc.*, 311 F.3d 1116, 1120 (Fed. Cir. 2002) (emphasis added). *See also Crown Operations Int'l, Ltd.*, 289 F.3d at 1357 ("An anticipating reference must describe the patented subject matter with sufficient clarity and detail to establish that the subject matter existed in the prior art and that such existence would be recognized by persons of ordinary skill in the field of the invention."); MPEP § 2131 ("The identical invention must be shown in as complete detail as is contained in the claim.").

"[T]he words of a claim 'are generally given their ordinary and customary meaning.'" *Phillips v. AWH Corporation*, 415 F.3d 1303, 1312 (Fed. Cir. 2005), *citing Vitrionics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir.1996). When interpreting a claim term, the inquiry must be based on "how a person of ordinary skill in the art would have understood [the] claim term[] at the time of the invention" (*Cook Biotech, Inc. v. Acell, Inc.*, 2006 U.S. App. LEXIS 21125 (Fed. Cir. 2006), *citing Pfizer, Inc. v. Teva Pharms., USA, Inc.*, 429 F.3d 1364, 1372-73 (Fed. Cir. 2005) (*citing Phillips*, 415 F.3d at 1313)) and can include such sources as "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." (*Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005)).

Claims 40, 42, 43, 111-118, 120, 127-131, 133 and 134 are not Anticipated by the '028 Patent

Claims 40, 42, 43, 111-118, 120, 127-131, 133 and 134 are rejected under 35 U.S.C. § 102(e) for anticipation by the '028 patent. Appellants respectfully disagree with the Examiner's

conclusion. Appellants separately address this ground of rejection as it applies to independent claims 40 and 43 and as it applies to independent claim 42.

The '028 Patent

The '028 patent discloses carbonated hydroxyapatite compositions that are formed by mixing dry ingredients (i.e., a phosphoric acid source, an alkali earth metal source, and a calcium carbonate) using mills or rollers "until a uniform dispersal of ingredients is obtained" (see, e.g., col. 4, lines 40-42, col. 5, lines 17-13, and col. 5, line 66, through col. 6, line 7, of the '028 patent). A lubricant is then added to the mixed dry ingredients in an amount to form a flowable "paste" or moldable "clay-like putty," which subsequently hardens (col. 6, lines 10-36, of the '028 patent). The '028 patent also discloses shaping the composition after formation of the flowable paste or putty, but prior to, during, or after hardening of the paste or putty (i.e., after hydration of the dry powder component; see col. 7, lines 60-62, of the '028 patent).

Claims 40 and 43

Independent claim 40, and claims dependent therefrom, recites a method of preparing a bioceramic composition by dry mixing powders of a calcium phosphate and a promoter, pressing the dry powders to form a compressed object of a predetermined shape, and hydrating the compressed powders to promote the formation of a PCA calcium phosphate. Independent claim 40 reads as follows:

40. A method of preparing a bioceramic composition, comprising the following steps:

a) dry mixing powders of a calcium phosphate and a promoter;

b) prior to hydration of said dry powders prepared in step (a), pressing said dry powders to form a compressed object of a predetermined shape; and

c) hydrating said compressed object of step (b) to form a reaction product, said reaction product comprising a poorly crystalline apatitic calcium phosphate. (Emphasis added.)

Independent claim 43 recites a bioceramic composition that includes dry powders of a calcium phosphate and a promoter that are compressed into an object of a predetermined shape. Independent claim 43 reads as follows:

43. A bioceramic composition comprising:

a compressed powder object of a predetermined shape,

said compressed powder object comprising dry powders of a calcium phosphate and a promoter,

wherein said promoter is selected to promote conversion of said calcium phosphate into a strongly bioresorbable, poorly crystalline apatitic calcium phosphate. (Emphasis added.)

The Examiner suggests that the '028 patent anticipates independent claim 43, and claims 127-131, 133 and 134 dependent therefrom, and independent claim 40, and claims 111-118 and 120 dependent therefrom, which are directed to a compressed powder object of a predetermined shape and a method for its manufacture and hydration, respectively. Specifically, the Examiner interprets the '028 patent as suggesting that the '028 patent

> shows use of dry mixed and compressed components (col 5, bottom – col 6, top), then hydrated, (col 4, lines 55-57) in situ...Examples show mixing, and milling, meeting the instant compression, since there is no claimed quantification of compression, while Constantz (Example 2, table 3) shows compressed products" (Office Action dated August 23, 2005, p. 3).

Appellants can find absolutely no teaching or suggestion in the '028 patent of a compressed powder object or a method for manufacturing a compressed powder object, as is recited in present claims 43 and 40, respectively, and claims dependent therefrom. The '028 patent nowhere discloses the formation of a compressed powder object with the specificity required to support an anticipation rejection under 35 U.S.C. § 102(e), as is suggested by the Examiner.

As is discussed above, the '028 patent clearly indicates that the dry ingredients are *mixed* using mills or rollers (see, e.g., col. 4, lines 40-42, col. 5, lines 17-13, and col. 5, line 66, through col. 6, line 7, of the '028 patent); the '028 patent fails to teach or suggest that the dry ingredients are *compressed*. Applicants note that because the phrase "compressed" is not defined in the specification, Applicants are entitled to use extrinsic evidence, e.g., a dictionary, to provide meaning to this phrase. (*Quantum Corp. v. Rodime, PLC*, 65 F.3d 1577, 36 USPQ2d 1162 (Fed. Cir. 1995), *cert. denied*, 517 U.S. 1167 (1996). "Absent ...a definition [in the patent or during prosecution] or evidence that the claim limitation as a whole has a special meaning to one of skill in the art, we see no error in the district court's use of dictionary definitions to ascertain the ordinary meaning of the relevant claim limitation."; *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 34 USPQ2d 1321 (Fed. Cir. 1995), (in banc), *aff'd*, 517 U.S. 370, 38 USPQ2d 1461 (1996). "Extrinsic evidence consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." "This evidence may be helpful to explain scientific principles, the meaning of technical terms, and terms of art that appear in the patent and prosecution history."; *Cybor Corp. v. FAS Technologies, Inc.*, 138 F. 3d 1448, 46 USPQ2d 1169 (Fed. Cir. 1998) (in banc) "A dictionary definition supports the interpretation of [a word]...in a patent's claims...(noting that, although technically extrinsic evidence, the court is free to consult dictionaries at any time to help

determine the meaning of claim terms."; *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250, 48 USPQ2d 1117, 1122 (Fed. Cir. 1998) "The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction.")

As the term is used in the present claims and understood by those skilled in the art, "compressed" powder objects result from pressing or squeezing powders together by applying force. As was discussed in the Reply to Office Action filed on July 3, 2003, "compressed" powder objects, as used in the present application and understood by those skilled in the art, result from pressing or squeezing powders by applying pressure. The term "compressed" is also defined by several extrinsic sources. *See, e.g.,* Random House Webster's Collegiate Dictionary 279 (1992) ("**compressed** – adj. 1. pressed into less space; condensed...2. pressed together...3. flattened as if by pressure."); McGraw Hill Dictionary of Scientific and Technical Terms 427 (5th ed. 1994) ("**compression**" - ...[MECH] Reduction in the volume of a substance due to pressure"). The claimed compressed powder objects are formed by subjecting powders of calcium phosphate and a promoter to pressure. Such pressure may be applied by, for example, a hand-held press or a hydraulic press (see, e.g., page 61, lines 19-27; page 88, line 20, through page 89, line 29). In contrast, the dry ingredients of the '028 patent are simply dispersed, not compressed. The '028 patent unambiguously states that:

> Any or all of the dry ingredients may be added prior to the initiation of mixing or prior to the completion of mechanical mixing. Methods of mixing can include ball milling, Brabender mixing, rolling between one or more rollers and a flexible container, or the like. Preferably, mixing will be thorough and will occur for a relatively short time or until a uniform dispersal of ingredients is obtained. (Col. 5, line 66, through col. 6, line 9.)

Thus, as is indicated by this passage, the '028 patent utilizes rolling and milling to intermix and disperse the dry ingredients rather than to compress the components together. The techniques

referred to in this passage are conventional techniques for making free-flowing powders, not compressed powder objects. Accordingly, the '028 patent fails to teach or suggest the claimed compressed powder objects, or methods of their manufacture, as is recited in present claims 43 and 40, respectively, and claims dependent therefrom.

The Examiner's contention that the '028 patent teaches compressed powder objects or methods for manufacturing compressed powder objects is based upon an incorrect interpretation of the '028 patent. Specifically, the Examiner ignores the explicitly-disclosed teaching that the components are "uniformly dispersed," as is clearly disclosed in the passage recited above. The Examiner has provided no basis for a conclusion that the '028 patent teaches compressing powders to form a compressed powder object, nor does the '028 patent itself suggest one. Therefore, the Examiner's basis for the present rejection of claims 40, 43, 111-118, 120, 127-131, 133, and 134 under 35 U.S.C. § 102(e) over the '028 patent is entirely contrary to numerous teachings in the specification of the '028 patent and to an understanding of the meaning of the term "compressed," as it is used in present claims 40, 43, 111-118, 120, 127-131, 133, and 134. This strained interpretation of the '028 patent cannot sustain the novelty rejection of the pending claims. Accordingly, Appellants respectfully request that the Board reverse the rejection of claims 40, 43, 111-118, 120, 127-131, 133, and 134 under 35 U.S.C. § 102(e) over the '028 patent.

Claim 42

Independent claim 42 recites a composite material that includes a PCA calcium phosphate and a biocompatible supplemental material selected from the materials recited in the claim. Independent claim 42 reads as follows:

42. A composite material, comprising:

a strongly bioresorbable, poorly crystalline apatitic calcium phosphate having a calcium to phosphate ratio (Ca/P) of less than 1.5 in contact with a biocompatible supplemental material,

wherein said supplemental material is a bioresorbable material selected from the group consisting of silk, demineralized bone matrix, hyaluronic acid and derivatives thereof, polyorthoesters, polyglycolic acid, polylactic acid, and copolymers thereof, polyesters of α-hydroxycarboxylic acids, poly(L-lactide) (PLLA), poly(D,L-lactide) (PDLLA), polyglycolide (PGA), poly(lactide-co-glycolide (PLGA), poly(D,L-lactide-co-trimethylene carbonate), and polyhydroxybutyrate (PHB), polyanhydrides, poly(anhydride-co-imide), and co-polymers thereof, and bioactive glass compositions;

a non-bioresorbable material selected from the group consisting of dextrans, polyethylene, polymethylmethacrylate (PMMA), carbon fibers, polyvinyl alcohol (PVA), poly(ethylene terephthalate)polyamide, bioglasses, and calcium phosphates;

a lubricant selected from the group consisting of silicone oil, polymer waxes, lipids, and fatty acids; or

a radiographic material; and

wherein said supplemental material is present in an amount effective to impart a characteristic selected from the group consisting of strength, resorption time, adherence, frictional characteristics, release kinetics, tensile strength, hardness, fracture toughness, elasticity, and imaging capability to said composite.

The Examiner rejects independent claim 42 under 35 U.S.C. § 102(e) for anticipation by the '028 patent, stating that "[a]s to stoichiometry, it is less than 1.5 Ca/P (col. 4, line 61). As to

supplemental materials, it can be collagen (col 6, bottom). Collagen is seen as meeting the requirements instantly claimed of adherence, tensile strength, and elasticity of the composite" (Office Action dated August 23, 2005, p. 3). Claim 42 recites all of the supplemental materials envisioned by Applicants and collagen is not one of those supplemental materials. Thus, Appellants respectfully submit that the Examiner's basis for the rejection of claim 42 is misplaced. The '028 patent merely discloses:

> Various additional components may be included during the formation of the carbonated hydroxyapatite, dahllite. Of particular interest are pharmacologically active agents, proteins, polysaccharides, or other biocompatible polymers, or the like. Of particular interest are proteins involved in skeletal structure such as different forms of collagen, especially Type I, fibrin, fibrinogen, keratin, tubulin, elastin, and the like, or structural polysaccharides, such as chitin. Pharmacologically active agents might include drugs that enhance bone growth, serve as a variety of cell growth factors, or act as anti-inflammatory or anti-microbial agents. Examples of such proteins might include but not be limited to: bone morphogenetic protein, cartilage induction factor, platelet derived growth factor, and skeletal growth factor. (See col. 6, line 61, through col. 7, line 5.)

Thus, Appellants note that while the '028 patent does disclose collagen as an additional component that can be added to a carbonated dahllite composition, collagen **is not recited** as a supplementary material in present claim 42. Thus, the disclosure of collagen as an additional component by the '028 patent fails to render claim 42 anticipated. Because the '028 patent fails to teach or suggest a composite material having any of the supplemental materials recited in claim 42, the '028 patent fails to teach or suggest all of the limitations of claim 42. Accordingly, Appellants respectfully request that the Board reverse the rejection of claims 42 under 35 U.S.C. § 102(e) over the '028 patent.

Claims 40, 42, 43, 111-114, 116-121, 124, 126-135, 138-140, 142, 143, 145, 146, 148, and 150-153 are not Anticipated by the '971 Patent

Claims 40, 42, 43, 111-114, 116-121, 124, 126-135, 138-140, 142, 143, 145, 146, 148, and 150-153 are rejected under 35 U.S.C. § 102(e) for anticipation by Constantz et al. (U.S. Patent No. 5,782,971; hereinafter "the '971 patent"). Appellants will discuss the rejection as it applies to independent claims 40 and 43, jointly, and to independent claims 42, 103, and 138, separately.

The '971 Patent

The '971 patent discloses the preparation of a calcium phosphate cement by combining:

> amorphous calcium phosphate, at least one additional calcium source, as well as a physiologically acceptable lubricant. Combination of the various components of the subject compositions produces a flowable, paste-like material capable of setting in vivo into a remodelable calcium phosphate, usually apatitic, product. Col. 2, lines 28-34.

The '971 patent further discloses testing the setting time of the calcium phosphate cement by filling Teflon ring molds with the calcium phosphate *paste*, allowing the paste to set, and determining the time required for setting (col. 7, line 46, through col. 8, line 23). The '971 patent also discloses testing the compressive strength of the hardened calcium phosphate cement by packing the calcium phosphate paste into a compression die, allowing the paste to set, and pressure testing the hardened cement (Col. 8, lines 32-60). In both instances, the '971 patent clearly indicates that a hydrated calcium phosphate *paste* is added to the mold and allowed to set.

Claims 40 and 43

Independent claims 40 and 43 are discussed *supra*. The Examiner rejects independent claims 40 and 43 on the basis that column 8 of the '971 patent discloses the preparation of "[a]

bioceramic of the instant claim 40...by dry mixing powders of Ca Phosphate (ACP) with promoters, Ca Carbonate, and supplemental materials, Ca phosphates then hydrated (col. 9, lines 29-39)." The Examiner further states that "Mixing of dry powders prior to liquid addition is disclosed as [sic: an] optional variation of the paste preparation (col. 5, line 1 1-28 [sic: 1-28]). The instant specification is no more explicit on this process as Constantz" (Office Action dated August 23, 2005, p. 3). As with the '028 patent discussed above, Appellants can find absolutely no teaching or suggestion in the '971 patent of a compressed powder object or a method for manufacturing a compressed powder object, as is recited in present claims 43 and 40, respectively, and claims dependent therefrom. In contrast to the '971 patent, claim 40 recites dry mixing powders of a calcium phosphate and a promoter, pressing the dry powders (prior to hydration) to form a compressed object of predetermined shape, and only then hydrating the compressed powder object. Similarly, claim 43 requires dry mixing powders of a calcium phosphate and a promoter that have been compressed to form a powder object having a predetermined shape; the compressed powder object prepared according to the method of claim 43 is not hydrated.

The '971 patent simply fails to describe a step in which the dry ingredients are mixed and compressed to form a compressed powder object of predetermined shape *prior to hydration.* In fact, like the '028 patent, the '971 patent fails to teach or suggest the formation of any compressed powder objects in the absence of hydration. Moreover, the '971 patent only discloses the mixing of dry ingredients followed by hydration with a lubricant, specifically to produce a **flowable** composition (see, e.g., col. 6, lines 12-21), not a compressed powder object, as is required by independent claims 40 and 43. Thus, the '971 patent lacks an express or inherent description of each and every element of independent claim 40, and claims 111-114,

116-121, 124, and 150 dependent therefrom, and independent claim 43, and claims 126-135, and 151 dependent therefrom, which is required for an anticipation (*see, e.g., Verdegaal Bros., Inc. v. Union Oil Co. of California, supra*). Because the '971 patent fails to teach or suggest the formation of a compressed powder object, much less the hydration of a compressed powder object, the '971 patent fails to disclose each and every method step of independent claims 40 and 43, and their dependent claims. For this reason, Appellants respectfully request that the Board reverse the rejection of claims 40, 43, 111-114, 116-121, 124, 126-135, and 150-151 under 35 U.S.C. § 102(e) over the '971 patent.

Claim 42

Independent claim 42 is discussed *supra*. The Examiner states that the '971 patent discloses "[a] number of supplemental agents...[to enhance] characteristics inclusive of resorption time, strength and other desirable properties and may include Ca sulfate, and phosphoric acid...Particulate extenders are at col. 6, top – calcium sulfate; Demineralized bone is matrix Gla – protein" (Office Action dated August 23, 2005, pages 3-4). The '971 patent does not teach or suggest all of the limitations of present claims 42, 152, and 153, and Appellants respectfully request reversal of this rejection.

Claim 42 recites several supplemental materials that can be included in the claimed PCA calcium phosphate. Calcium sulfate, which is one of the supplemental agents disclosed by the '097 patent and relied on by the Examiner in forming the § 102(e) rejection, is not recited in claim 40. Thus, the disclosure of calcium sulfate as a particulate extender by the '971 patent cannot serve as the basis for a rejection of claims 42, 152, and 153 under 35 U.S.C. § 102(e). The Examiner also rejects claims 42, 152, and 153 based on a disclosure in the '971 patent of the

addition of matrix Gla-protein. As was discussed in the Reply to Non-Final Office Action, dated June 3, 2005, matrix Gla-protein is not the same as demineralized bone matrix. Matrix Gla-protein is 14-kD extracellular matrix **protein** of the mineral-binding Gla protein family, which can be further described as a γ-carboxyglutamic acid (Gla)–rich, vitamin K–dependent and apatite-binding protein. In contrast, demineralized bone matrix is a complex composition containing approximately 99% **non-protein** matrix components and only about 1% protein components; the components, many of which are unknown, are provided in a substantially impure form. Thus, demineralized bone matrix and matrix Gla-protein are not the same. Furthermore, the '971 patent only discloses the addition of:

> specific proteins of interest includ[ing] osteonectin, bone sialoproteins (Bsp), α-2HS-glycoproteins, bone Gla-protein (Bgp), matrix Gla-protein, bone phosphoglycoprotein, bone phosphoprotein, bone proteoglycan, protolipids, bone morphogenic protein, cartilage induction factor, platelet derived growth factor, skeletal growth factor, and the like. Col. 5, line 67, through col. 6, line 6; emphasis added.

The '971 patent only discloses the use of specific proteins, not a complex consisting of primarily non-protein components. Because the '971 patent fails to teach or suggest that the additive could be demineralized bone matrix, a substantially impure, heterogeneous composition that consists of primarily non-proteinaceous components, the disclosure of matrix Gla-protein by the '971 patent fails to teach or suggest all of the elements of present claims 42, 152, and 153.

Because the '971 patent fails to disclose a PCA calcium phosphate composition containing any of the supplemental materials recited in claim 40, the rejection of claims 42, 152, and 153 under 35 U.S.C. § 102(e) over the '971 patent should be reversed.

Claim 103

Independent claim 103 recites a method for treating a bone defect by identifying a bone site for receiving an implant and introducing a compressed powder object at the implant site. Independent claim 103 reads as follows:

103. A method for treating a bone defect comprising:

identifying a bone site for receiving an implant;

introducing a compressed powder object at the bone site, said compressed powder object comprising dry powders of a calcium phosphate and a promoter and having approximately the shape required for repair of the bone defect,

whereby said compressed powder object is converted *in vivo* upon hydration at the implantation site into a strongly bioresorbable poorly crystalline apatitic calcium phosphate.

The Examiner rejects independent claim 103 for lack of novelty in view of the '971 patent for the reasons discussed above, to wit, that the '971 patent describes dry mixing powders of a calcium phosphate (see, e.g., Office Action dated August 23, 2005, p. 3). For the reasons discussed above, the '971 patent fails to teach or suggest all of the limitations of present independent claim 103. Independent claim 103, like independent claims 40 and 43, require the use of a compressed powder object. The compressed powder object is introduced at a bone site and is hydrated *in vivo*; hydration converts the compressed powder object into a PCA calcium phosphate. Claim 103 clearly indicates that the compressed powder object is prepared by compressing, not mixing, dry powders of a calcium phosphate and a promoter (in the absence of a liquid component) and that hydration occurs at a later time (i.e., following introduction to a bone site). As is discussed above, the '971 patent fails to teach or suggest the preparation of a

compressed powder object, much less the subsequent hydration of a compressed powder object. For this reason, the rejection of claim 103 under 35 U.S.C. § 102(e) for anticipation by the '971 patent should be reversed.

Claim 138

Independent claim 138 is directed to a method for preparing a bioceramic composition by mixing a calcium phosphate powder with the powder of a promoter selected from calcium metaphosphate, dicalcium phosphate dihydrate, heptacalcium decaphosphate, calcium pyrophosphate dihydrate, poorly crystalline apatitic (PCA) calcium phosphate, calcium pyrophosphate, monetite, octacalcium phosphate, CaO, calcium acetate, H_3P0_4, and amorphous calcium phosphate in a hydrating medium to form a paste, introducing the paste into a mold that approximates a desired implant shape, and allowing the paste to harden into a PCA calcium phosphate article. Independent claim 138 reads as follows:

138. A method of preparing a bioceramic implant composition, comprising:

mixing powders of a calcium phosphate and a promoter selected from calcium metaphosphate, dicalcium phosphate dihydrate, heptacalcium decaphosphate, calcium pyrophosphate dihydrate, poorly crystalline apatitic (PCA) calcium phosphate, calcium pyrophosphate, monetite, octacalcium phosphate, CaO, calcium acetate, H_3PO_4, and amorphous calcium phosphate in a hydrating medium to form a paste, said promoter selected to convert the mixed powders into a poorly crystalline apatitic calcium phosphate;

introducing said paste into a mold that approximates a desired implant shape; and allowing said paste to harden.

The method of claim 138 yields a bioceramic implant composition which can be used by the skilled artisan to prepare an implant having the approximate size and shape needed to replace or repair a defect, e.g., a bone defect, in a patient; the skilled artisan would not have to mold the implant during surgery using, e.g., a moldable paste. The Examiner argues that the '971 patent anticipates claim 138, and claims 139-140, 142, 143, 145, 146, and 148 dependent therefrom, because the '971 patent discloses the use of a die to permit the formation of a predetermined, shaped article (Office Action dated December 17, 2004, p. 3); the Examiner did not provide any further reasons for the rejection of independent claim 138 and its dependent claims in the Office Action dated August 23, 2005 other than to state that the "products [envisioned by the '971 patent] are bioresorbable, biocompatible, applicable as a paste in vivo (col. 6, lines 1 1-39 [sic: 1-39], to harden, or can be used as implants, or prosthetic devices (last paragraph, col. 6)" (*see* page 4).

As was discussed in the Reply to Non-Final Office Action dated June 3, 2005, the method of independent claim 138 was amended to require that the calcium phosphate paste be introduced into a mold that "approximates a desired implant shape." The '971 patent fails to teach or suggest this limitation. The '971 patent merely discloses the use of a mold or compression die for preparing a hardened calcium phosphate, which can be subsequently tested to determine its compression strength. The '971 patent fails to teach or suggest that the mold or compression die is used to prepare a calcium phosphate bioceramic implant composition having a desired shape for implantation or that one skilled in the art should use a mold that would allow the calcium phosphate paste to harden in a desired shape for implantation. Absent this teaching or suggestion, the '971 patent fails to teach or suggest all of the limitations of present claim 138,

and claims dependent therefrom. For this reason, the rejection of claims 138-140, 142, 143, 145, 146, and 148 under 35 U.S.C. § 102(e) for anticipation by the '971 patent should be reversed.

2. The Obviousness Rejections

The Legal Standard for Obviousness Under 35 U.S.C. § 103(a)

A claimed invention is unpatentable if the differences between it and the prior art are such that the claimed subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *See* 35 U.S.C. § 103(a) (2003). Correspondingly, the conclusion regarding obviousness of a claimed invention is based upon the following four factual inquiries: (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the pertinent art; and (4) secondary considerations of nonobviousness (*e.g.,* commercial success, long-felt but unsolved needs, failure of others). *See McNeil-PPC, Inc. v. L. Perrigo Co.*, No. 02-1516, 2003 U.S. App. LEXIS 15442, at *14, -- F.3d -- (Fed. Cir. Aug. 1, 2003) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966)); *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1124 (Fed. Cir. 2000) (same); *Ex Parte Crinion*, No. 2001-0210, 2002 WL 31257831, at *2 (Bd. Pat. App. & Interf. 2001) (same); MPEP § 2141.

Three criteria are required to establish a *prima facie* case of obviousness:

First, "[t]here must be a teaching or suggestion within the prior art, within the nature of the problem to be solved, or within the general knowledge of a person of ordinary skill in the field of the invention, to look to particular sources, to select particular elements, and to combine them as combined by the inventor." *Id.* at 1376. *See also Brown & Williamson Tobacco Corp.*,

229 F.3d at 1124-25 ("[A] showing of a suggestion, teaching or motivation to combine the prior art references is an essential evidentiary component of an obviousness holding. This evidence may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved." (internal citations omitted)); *Ex Parte Metcalf*, 67 U.S.P.Q.2d 1633, 1635 (Bd. Pat. App. & Interf. 2003) ("Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination."); MPEP § 2143.01. The "[d]etermination of obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention." *Crown Operations Int'l, Ltd.*, 289 F.3d at 1376.

The requisite teaching, suggestion, or motivation must be "clear and particular;" broad conclusory statements will not suffice. *See Brown & Williamson Tobacco Corp.*, 229 F.3d at 1125; *In re Kotzab*, 217 F.3d 1365, 1370 (Fed. Cir. 2000) ("Whether the Board relies upon an express or implicit showing, it must provide particular findings related thereto. Broad conclusory statements are not 'evidence.'" (internal citations omitted)). A statement that modification of the prior art would have been "within the capabilities of one skilled in the art" will not, therefore, suffice to establish a *prima facie* case of obviousness. *See In re Kotzab*, 217 F.3d at 1371 (reversing the Board's finding of obviousness, stating that "there was no finding as to the specific understanding or principle within the knowledge of a skilled artisan that would have motivated one with no knowledge of [the inventor's] invention to make the combination in the manner claimed."); *Al-Site Corp. v. VSI Int'l, Inc.*, 174 F.3d 1308, 1324 (Fed. Cir. 1999) ("Rarely, however, will the skill in the art component operate to supply missing knowledge or prior art to reach an obviousness judgment."); MPEP § 2143.01. As the Board itself stated in

overturning an examiner's obviousness rejections based on a proposed modification of the prior art:

> In this case, however, the only suggestion for the examiner's combination of the isolated teachings of the applied references improperly stems from appellant's disclosure and not from the applied prior art. *At best, the examiner's comments regarding obviousness amount to an assertion that one of ordinary skill in the relevant art would have been able to arrive at appellant's invention because he had the necessary skills to carry out the requisite process steps. This is an inappropriate standard for obviousness. That which is within the capabilities of one skilled in the art is not synonymous with obviousness.* That one can reconstruct and/or explain the theoretical mechanism of an invention by means of logic and sound scientific reasoning does not afford the basis for an obviousness conclusion unless that logic and reasoning also supplies sufficient impetus to have led one of ordinary skill in the art to combine the teachings of the references to make the claimed invention. *Ex Parte Levengood*, 28 U.S.P.Q.2d 1300, 1301-02 (Bd. Pat. App. & Interf. 1993) (internal citations omitted; emphasis added)).

Second, there must be a reasonable expectation of success that modification or combination of the prior art will achieve the claimed invention. *See Brown & Williamson Tobacco Co.*, 229 F.3d at 1125 ("[T]he ultimate determination of obviousness does not require absolute predictability of success. All that is required is a reasonable expectation of success." (internal references omitted)); MPEP § 2143.02. There can be neither a motivation to modify or combine prior art nor a reasonable expectation of success when doing so would alter the principles of operation underlying that art. *See* MPEP § 2143.01.

Third, the prior art reference(s) must teach or suggest all the claim limitations. *See* MPEP § 2143.03.

Claims 40, 42, 43, 103, 111-121, 123-135, 138-143, 145, 146, 148, and 150-153 are Not Obvious Over the '971 Patent in combination with the '162 Patent

Claims 40, 42, 43, 103, 111-121, 123-135, 138-143, 145, 146, 148, and 150-153 are rejected under 35 U.S.C. § 103(a) for obviousness over the '971 patent in combination with the

'162 patent.[1] Appellants will discuss the rejection as it applies to independent claims 40 and 43, jointly, and to independent claims, 42, 103, and 138, separately.

The '971 Patent

The '971 patent is discussed *supra*.

The '162 Patent

The '162 patent discloses the conventional milling of a basic calcium phosphate source, e.g., a crystalline calcium phosphate, with phosphoric acid, which modifies the calcium to phosphate ratio of the calcium source and promotes its conversion through an acid/base reaction to a poorly crystalline or amorphous calcium phosphate. The resulting powder, when hydrated, subsequently hardens to form "a number of stable compounds, including monetite, brushite, octacalcium phosphate, calcium-deficient hydroxyapatite, stoichiometric hydroxyapatite (1.67:1), or mixtures of the aforementioned minerals, in addition to various metastable amorphous calcium phosphates" (see col. 3, lines 27-34). The '162 patent discloses that

> The particular manner in which the various dry ingredients are combined is not critical to this invention, so long as intimate mixing occurs, partial reaction may proceed between the ingredients without complete reaction. Alternatively, it may be desirable to mix or mill the calcium sources by one process and combine them with the phosphate sources and/or phosphate additive via another mixing or milling process. Techniques which may be used include amalgamator (wig-l-bug), ball milling, Brabender mixing, blender, rolling between one or two rollers in a flexible container, or the like. Various equipment may be used, including ball mills, mortar and pestle, planetary mills, centrifugal mills, mechanofusion systems, air pulverizers, jet mills, vibratory mills, colloid mills, attrition mills, disc mills, and the like. (*See* col. 4, lines 38-51; emphasis added.)

[1] Appellants note that independent claim 42 is not listed among the claims rejected for obviousness over the '971 patent in combination with the '162 patent in the Office Action dated August 23, 2005. Because independent claim 42 was previously included in this rejection (*see* Office Action dated December 17, 2004) and because claims 152 and 153 dependent from claim 42 are included in the rejection, Appellants discuss the rejection as it applies to independent claim 42.

Once milled, the '162 patent teaches that "[t]he dry material will be combined with a physiologically acceptable lubricant, conveniently an aqueous lubricant, e.g., sterile water, comprising the base" (*see* col. 5, lines 58-60).

Claims 40 and 43

Independent claims 40 and 43 are discussed *supra*. The Examiner states that "Constantz...is seen as obvious, since...Constantz uses the instant components, mixed as powders, with lubricant fluids added to provide wet mixing, or added after mixing, followed by compression" (Office Action dated August 23, 2005, p. 4). As is emphasized above, independent claims 40 and 43 require dry mixing of a calcium phosphate powder with a powder of a promoter; the powders are subsequently pressed to form a compressed powder object of a predetermined shape. Claims 40 and 43 specify that the powders are dry, thus, the compressed powder object is necessarily formed in the absence of a fluid. Step (c) of claim 40 further requires hydration of the compressed powder object, nonetheless, the compressed powder object of both claims 40 and 43 are formed from dry powders that are pressed together, not mixed, prior to a hydration step.

As is discussed above, the '971 patent merely discloses the wet or dry mixing of calcium phosphate components; the '971 patent fails to teach or suggest the preparation of a compressed powder object by pressing dry powders. Indeed, the Examiner acknowledges this distinction by stating that the '971 patent discloses a compression step only after the "wet mixing" of components or the addition of "lubricant fluids...after mixing" of dispersed dry powder components (Office Action dated August 23, 2005, p. 4). Thus, the '971 patent fails to teach or suggest all of the limitations of independent claims 40 and 43, and claims dependent therefrom.

The '162 patent, which the Examiner combines with the '971 patent, fails to remedy the deficiencies of the '971 patent. The '162 patent, like the '971 patent, only discloses the wet or dry mixing of calcium phosphate components (see, e.g., col. 2, lines 52-61; col. 3, lines 1-16; col. 4, lines 17-51; and col. 7, lines 17-30). The '162 patent nowhere teaches or suggests the pressing of dry calcium phosphate powders to prepare a compressed powder object having a predetermined shape. Thus, both the '971 patent and the '162 patent fail to teach or suggest all of the limitations of independent claims 40 and 43, and claims dependent therefrom. For this reason, the rejection of claims 40, 43, 111-121, 123-135, and 150-151 under 35 U.S.C. § 103(a) for obviousness over the '971 patent in combination with the '162 patent should be reversed.

Claim 42

Independent claim 42 is discussed *supra*. The Examiner rejects claims 42, 152, and 153, stating that while "not all supplemental components instantly claimed are discussed [in the '971 patent]...[t]hese components are optional additives used for their intended purposes to optimize the invention, & are given no patentable weight. However, 6005162 show them (col. 5, lines 43-line 67, col. 7)" (Office Action dated August 23, 2005, p. 4). This rejection is in error and should be reversed.

As is discussed above, the '971 patent fails to teach or suggest a composite material that includes a strongly bioresorbable, PCA calcium phosphate having a calcium to phosphate ratio (Ca/P) of less than 1.5 in contact with any of the biocompatible supplemental materials recited in independent claim 42. The '162 patent again fails to remedy the deficiencies of the '971 patent as to the limitations of independent claim 42. The Examiner suggests that while not all of the supplemental materials are shown in the '971 patent, at least some of the supplemental materials

are disclosed by the '162 patent. Appellants can discern absolutely no teaching or suggestion by the '162 patent as to any of the supplemental materials recited in independent claim 42. The Examiner directs Appellants to col. 5, lines 43-67, and col. 7 of the '162 patent, but the passages found there disclose nothing more than that found in the '971 patent, which, as is discussed above, does not disclose any of the supplemental materials recited in independent claim 42. Thus, neither the '971 patent nor the '162 patent, either singly or in combination, teach or suggest each and every element of independent claim 42, and claims 152 and 153 dependent therefrom. For this reason, the rejection of claims 42, 152, and 153 under 35 U.S.C. § 103(a) for obviousness over the '971 patent in combination with the '162 patent should be reversed.

Claim 103

Independent claim 103 is discussed *supra*. The Examiner rejects independent claim 103 for obviousness over the '971 patent in combination with the '162 patent. This rejection is in error and should be reversed.

As is discussed above, the '971 patent fails to teach or suggest all of the limitations of present independent claim 103 because the '971 patent does not disclose the preparation of a compressed powder object, much less the introduction of a compressed powder object, according to the method of independent claim 103, at a bone site requiring treatment.

The '162 patent fails to remedy the deficiencies of the '971 patent. The '162 patent merely discloses the mixing and milling of calcium phosphate powders; it does not teach or suggest pressing these powders together to form a compressed powder object. Absent a teaching or suggestion to prepare a compressed powder object, neither the '971 patent nor the '162 patent teach or suggest, either expressly or inherently, each and every limitation of independent claim

103. Furthermore, the Examiner has not pointed to any portion of either the '971 patent or the '162 patent that discloses this element of independent claim 103. Accordingly, Appellants respectfully request that the Board reverse the rejection of claim 103 under § 103(a) for obviousness over the '971 patent in combination with the '162 patent.

Claim 138

Independent claim 138 is discussed *supra*. The Examiner rejects claims 138-143, 145, 146, and 148 under § 103(a) for obviousness over the '971 patent in combination with the '162 patent, but fails to provide any specific reasons for the rejection. This rejection is in error and should be reversed.

As is discussed above, independent claim 138, and claims dependent therefrom, which are directed to the formation of a bioceramic implant composition, require the mixing of powders of a calcium phosphate and a promoter selected from calcium metaphosphate, dicalcium phosphate dihydrate, heptacalcium decaphosphate, calcium pyrophosphate dihydrate, poorly crystalline apatitic (PCA) calcium phosphate, calcium pyrophosphate, monetite, octacalcium phosphate, CaO, calcium acetate, H_3PO_4, and amorphous calcium phosphate in a hydrating medium to form a paste. The paste is then introduced into a mold that approximates a desired implant shape and the paste is allowed to harden. As is discussed above, the '971 patent fails to teach or suggest the preparation of a bioceramic implant composition by introducing a calcium phosphate paste to a mold that approximates a desired implant shape. The '971 patent merely discloses the use of a mold or compression die for preparing a hardened calcium phosphate solely for the purpose of determining the compression strength of the hardened calcium phosphate. The '971 patent fails to teach or suggest that the mold or compression die

approximate the shape of a desired implant or that one skilled in the art should use the mold or compression die to prepare a hardened calcium phosphate in a desired shape for implantation. Thus, the '971 patent fails to teach or suggest all of the limitations of independent claim 138, and claims dependent therefrom.

To remedy the deficiencies of the '971 patent, the Examiner combines it with the '162 patent. Like the '971 patent, the '162 patent merely discloses the use of a mold or compression die for preparing a hardened calcium phosphate; the sole purpose of the mold and compression die is to test the compression strength of the hardened calcium phosphate (*see*, e.g., col. 8, line 65, through col. 9, line 55). The '162 patent also fails to teach or suggest the preparation of a mold that approximates a desired implant shape for use in the preparation of a bioceramic implant composition, as is required by independent claim 138. Thus, the '162 patent fails to teach or suggest all of the elements of claims 138-143, 145, 146, and 148, and fails to remedy the deficiencies of the '971 patent

Because neither the '971 patent nor the '162, either alone or in combination, teach or suggest all of the elements of independent claim 138, Appellants respectfully request that the Board reverse the rejection of claims 138-143, 145, 146, and 148 under § 103(a) for obviousness over the '971 patent in combination with the '162 patent.

3. The Double Patenting Rejections.

The Double Patenting Rejection Of Claims 43, 127, 128, 133, and 135 Has Been Overcome By the Terminal Disclaimer Submitted Herewith, The Entry Of Which Is Respectfully Requested

In the August 23, 2005 Office Action, the Examiner reiterated the rejection of claims 43, 127, 128, 133, and 135 under the judicially-created doctrine of obviousness-type double

patenting over claims 1 and 3 of the '594 patent (previously claims 18 and 21 of U.S. Serial No. 09/993,739). As is indicated above, Appellants have filed herewith an Amendment requesting entry of a Terminal Disclaimer disclaiming patent term extending beyond the expiration dates of the '594 patent. As entry of the Terminal Disclaimer removes an issue from appeal, Appellants submit that its entry is appropriate. *See* MPEP § 1207. Accordingly, Appellants respectfully request that the Board withdraw the double patenting rejection of claims 43, 127, 128, 133, and 135.

CONCLUSION

For all the reasons provided above, the real party in interest, Etex Corporation, a small entity, requests that the Board reverse the Examiner's rejections of pending claims 40, 42, 43, 103, 111-135, 138-143, 145, 146, 148, and 150-153.

A check for $250.00 in payment of the fee required by 37 C.F.R. § 41.20(b)(2) was provided on September 26, 2006.

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully Submitted,

Todd Armstrong, Ph.D.
Reg. No. 54,590

Date: 17 May 2007

For _____
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Claims Appendix:

Claims on Appeal

40. A method of preparing a bioceramic composition, comprising the following steps:

a) dry mixing powders of a calcium phosphate and a promoter;

b) prior to hydration of said dry powders prepared in step (a), pressing said dry powders to form a compressed object of a predetermined shape; and

c) hydrating said compressed object of step (b) to form a reaction product, said reaction product comprising a poorly crystalline apatitic calcium phosphate.

42. A composite material, comprising:

a strongly bioresorbable, poorly crystalline apatitic calcium phosphate having a calcium to phosphate ratio (Ca/P) of less than 1.5 in contact with a biocompatible supplemental material,

wherein said supplemental material is a bioresorbable material selected from the group consisting of silk, demineralized bone matrix, hyaluronic acid and derivatives thereof, polyorthoesters, polyglycolic acid, polylactic acid, and copolymers thereof, polyesters of α-hydroxycarboxylic acids, poly(L-lactide) (PLLA), poly(D,L-lactide) (PDLLA), polyglycolide (PGA), poly(lactide-co-glycolide (PLGA), poly(D,L-lactide-co-trimethylene carbonate), and polyhydroxybutyrate (PHB), polyanhydrides, poly(anhydride-co-imide), and co-polymers thereof, and bioactive glass compositions;

a non-bioresorbable material selected from the group consisting of dextrans, polyethylene, polymethylmethacrylate (PMMA), carbon fibers, polyvinyl alcohol (PVA), poly(ethylene terephthalate)polyamide, bioglasses, and calcium phosphates;

a lubricant selected from the group consisting of silicone oil, polymer waxes, lipids, and fatty acids; or

a radiographic material; and

wherein said supplemental material is present in an amount effective to impart a characteristic selected from the group consisting of strength, resorption time, adherence, frictional characteristics, release kinetics, tensile strength, hardness, fracture toughness, elasticity, and imaging capability to said composite.

43. A bioceramic composition comprising:

a compressed powder object of a predetermined shape,

said compressed powder object comprising dry powders of a calcium phosphate and a promoter,

wherein said promoter is selected to promote conversion of said calcium phosphate into a strongly bioresorbable, poorly crystalline apatitic calcium phosphate.

103. A method for treating a bone defect comprising:

identifying a bone site for receiving an implant;

introducing a compressed powder object at the bone site, said compressed powder object comprising dry powders of a calcium phosphate and a promoter and having approximately the shape required for repair of the bone defect,

whereby said compressed powder object is converted *in vivo* upon hydration at the implantation site into a strongly bioresorbable poorly crystalline apatitic calcium phosphate.

111. The method of claim 40, wherein following said hydrating said compressed object hardens in an endothermic reaction.

112. The method of claim 40, wherein said hydrating further comprises incubating the compressed object at about 37 °C.

113. The method of claim 40, wherein said hydrating is carried out *in vivo*.

114. The method of claim 40, wherein said hydrating comprises using a hydration medium to hydrate said compressed object,

wherein said hydration medium is selected from the group consisting of physiological fluids, serum culture medium, and tissue culture medium.

115. The method of claim 40, further comprising lyophilizing said reaction product.

116. The method of claim 40, further comprising contacting said powders with a biologically active agent.

117. The method of claim 116, wherein said biologically active agent is selected from the group consisting of antibiotics, bone morphogenic protein, bone regenerative proteins, and vaccines.

118. The method of claim 40, wherein said promoter is selected from the group consisting of calcium metaphosphate, dicalcium phosphate dihydrate, heptacalcium decaphosphate, tricalcium phosphates, calcium pyrophosphate dihydrate, crystalline hydroxyapatite, PCA calcium pyrophosphate, monetite, octacalcium phosphate, CaO, $CaC0_3$, calcium acetate, and H_3PO_4, and amorphous calcium phosphate.

119. The method of claim 40, wherein said promoter comprises dicalcium phosphate dihydrate (DCPD).

120. The method of claim 40, further comprising the step of mixing a supplemental material with said powders.

121. The method of claim 120, wherein said supplemental material is demineralized bone.

122. The method of claim 40 wherein said poorly crystalline apatitic (PCA) calcium phosphate has an X-ray diffraction pattern comprising broad peaks at 2θ values of 26°, 28.5°, 32°, and 33°.

123. The method of claim 40, wherein said poorly crystalline apatitic (PCA) calcium phosphate is further characterized in that when at least one gram of said poorly crystalline apatitic (PCA) calcium phosphate is implanted at a rat intramuscular site, at least 80% of said poorly crystalline apatitic (PCA) calcium phosphate is resorbed within one year.

124. The method of claim 40, wherein said calcium phosphate comprises amorphous calcium phosphate.

125. The composition of claim 43, wherein said poorly crystalline apatitic (PCA) calcium phosphate is further characterized in that when at least one gram of said strongly bioresorbable, poorly crystalline apatitic (PCA) calcium phosphate is implanted at a rat intramuscular site, at least 90% of said strongly bioresorbable, poorly crystalline apatitic (PCA) calcium phosphate is resorbed within one year.

126. The composition of claim 43, wherein said calcium phosphate comprises amorphous calcium phosphate.

127. The composition of claim 43, wherein said object further comprises a hydration medium to hydrate the object.

128. The composition of claim 127, wherein said hydration medium is selected from the group consisting of physiological fluids, serum culture medium, and tissue culture medium.

129. The composition of claim 43, wherein said conversion is characterized by an endothermic reaction.

130. The composition of claim 43, further comprising a biologically active agent.

131. The composition of claim 130, wherein said biologically active agent is selected from the group consisting of antibiotics, bone morphogenic protein, bone regenerative proteins, and vaccines.

132. The composition of claim 43, wherein said promoter comprises dicalcium phosphate dihydrate (DCPD).

133. The composition of claim 43, wherein said promoter is selected from the group consisting of calcium metaphosphate, dicalcium phosphate dihydrate, heptacalcium decaphosphate, tricalcium phosphates, calcium pyrophosphate dihydrate, crystalline hydroxyapatite, PCA calcium phosphate, calcium pyrophosphate, monetite, octacalcium phosphate, CaO, $CaC0_3$, calcium acetate, H_3PO_4, and amorphous calcium phosphate.

134. The composition of claim 43, further comprising a supplemental material.

135. The composition of claim 134, wherein said supplemental material is demineralized bone matrix.

136. The composition of claim 127, wherein said poorly crystalline apatitic calcium phosphate has an x-ray diffraction pattern comprising broad peaks at 2θ values of 26° , 28.5° , 32° and 33°.

137. The composition of claim 127, wherein said poorly crystalline apatitic calcium phosphate is further characterized in that when at least one gram of said strongly bioresorbable, poorly crystalline apatitic (PCA) calcium phosphate is implanted at a rat intramuscular site, at least 90% of said strongly bioresorbable, poorly crystalline apatitic (PCA) calcium phosphate is resorbed within one year.

138. A method of preparing a bioceramic implant composition, comprising:

mixing powders of a calcium phosphate and a promoter selected from calcium metaphosphate, dicalcium phosphate dihydrate, heptacalcium decaphosphate, calcium pyrophosphate dihydrate, poorly crystalline apatitic (PCA) calcium phosphate, calcium pyrophosphate, monetite, octacalcium phosphate, CaO, calcium acetate, H_3PO_4, and amorphous calcium phosphate in a hydrating medium to form a paste, said promoter selected to convert the mixed powders into a poorly crystalline apatitic calcium phosphate;

introducing said paste into a mold that approximates a desired implant shape; and allowing said paste to harden.

139. The method of claim 138, further comprising incubating said paste at about 37° C.

140. The method of claim 138, wherein said hydrating medium is selected from the group consisting of water, physiologically acceptable pH-buffered solutions, saline solution, serum culture medium, and tissue culture medium.

141. The method of claim 138, further comprising lyophilizing said article.

142. The method of claim 138, further comprising contacting said powders with a biologically active agent.

143. The method of claim 142, wherein said biologically active agent is selected from the group consisting of antibiotics, bone morphogenic protein, bone regenerative proteins, and vaccines.

145. The method of claim 138, further comprising the step of adding a supplemental material to said mixed powders.

146. The method of claim 145, wherein said supplemental material is demineralized bone matrix.

147. The method of claim 138, wherein said poorly crystalline apatitic calcium phosphate (PCA) has an x-ray diffraction pattern comprising broad peaks at 2θ values of 26°, 28.5°, 32° and 33°.

148. The method of claim 138, wherein said calcium phosphate comprises amorphous calcium phosphate.

149. The method of claim 40, wherein said powders are compressed using a hydraulic press.

150. The method of claim 40, wherein said powders are compressed under a pressure in the range of about 500 psi to about 5000 psi.

151. The composition of claim 43, wherein said compressed powder object has a density ranging from about 1.2 g/cm^3 to about 2.0 g/cm^3.

152. The composite material of claim 42, wherein the supplementary material is in the form selected from the group consisting of a sponge, mesh, a film, a fiber, a gel, a filament, and a particle.

153. The composite material of claim 42, wherein said supplementary material is demineralized bone matrix.

Related Proceedings Appendix

A related application, U.S. Serial No. 10/222,670, is on appeal. There are currently no pending interferences related to this case.

Evidence Appendix

None.